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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,674	11/17/1999	MARK E. LEWIS	6622.US.01	4770

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ABBOTT LABORATORIES  
DEPT. 377 - AP6D-2  
100 ABBOTT PARK ROAD  
ABBOTT PARK, IL 60064-6050

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

12

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/441,674

Applicant(s)

LEWIS ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

This Office Action is in response to Applicants' amendment filed March 5, 2002 and entered as Paper No. 11. Claims 1-28 are pending.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 9, 10, 12-18, 21-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,580,794 to Allen (hereinafter Allen '794).

Applicants' invention is directed to a test strip for use in combination with a measuring device comprising a support, at least one reaction area, and an indicator.

29 Allen '794 teaches a disposable electronic assay device. The device comprises a test  
33 strip containing a sample receptor for receiving a sample to be tested, a sample treatment  
34 element for reaction with the sample to yield a detectable change, an electrical signal produced  
35 by a detector to correlate the amount of analyte in the sample, and a signal processor for  
36 outputting a visually readable result. See abstract. The test strip (10) has a pair of electrodes  
37 (12) mounted between the sample receptor zone (14) and the reagent zone (16). (col. 7, line 62  
38 – col. 8, line 15). The reagents may be dry formulated on a matrix which can be a bibulous  
39 material such as porous plastic (col. 10, lines 33-43). The reagent zone may comprise reagents  
such as enzymes, antibodies, antigens, etc. (col. 16, lines 16-21). The detectable change is a  
change in reflectivity, transmission or electrical current (col. 7, lines 41-61). The signal  
which include 34

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processing means may include an analog to digital conversion means. Assays for glucose, cholesterol, triglycerides, etc. may be detected by the devices. In addition, single or multiple assays can be done at one time.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Allen '794.

3. Claims 1-8, 10-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,812,590 to Gunasingham (hereinafter Gunasingham '590).

Gunasingham '590 teaches a device for detecting chemical species in liquids.

30-  
32  
material  
worked on  
29  
33-39  
41-43  
mwo  
44-62  
52-54  
mwo

The test device comprises measuring electrodes (2) and reference electrodes (4) coated with a reaction layer (11) and a membrane layer (12). At least one of the electrodes is made by screen-printing carbon ink onto the base strip (1) (col. 6, lines 35-37). Each of the electrodes is made of gold, platinum, silver, graphite, etc. The measuring apparatus used in conjunction with the test device connects to the reference/working electrode pairs. The device is used in sensing blood glucose levels using the enzyme glucose oxidase.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102, in view of the teachings of Gunasingham '590.

### ***Response to Arguments***

4. Applicant's arguments filed March 5, 2002 have been fully considered but they are not persuasive. Applicants' arguments concerning the rejections given in the previous Office Action and restated above are seemingly directed to the function of each of the structures recited in the claimed invention. Specifically, Applicants argue that neither Allen '794, nor

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Gunasingham '590 teach devices which have a test strip and/or test port that selects a particular assay to be performed at a particular time. In Allen, the reference clearly teaches that single or multiple assays can be performed at one time. Also, Gunasingham teaches detection of multiple species in Example 4. Applicants' concern is that the claims recite "sensor capable of interacting with said test port to select one of a multiplicity of testing functionalities" and also a "test port comprising a sensor capable of interacting with said indicators on said test strip to select one of multiplicity of testing functionalities". Applicants seemingly believe that "means plus function" applies here; however, it does not. To invoke "mean plus function" under 35 USC 112, 6<sup>th</sup> paragraph, one must meet a three prong test, the first test requiring the phrase "means for" or "step for" to be present in the claim. Since none of the claims recite such language, means plus function is not invoked. Thus, in examining the claims for patentability, the Examiner considers the structure of the device, not the function of its parts. Both the Allen '794 and Gunasingham '590 references meet Applicants' claimed limitations. Both rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

July 13, 2002

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700